IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Lasheena Sipp-Lipscomb and Andres Gardin, Sr., Individually and in their own right and as Parents and Natural Guardians of A G, Jr., a Minor v.

Civil Action No. 2:20-cv-01926-MMB

Einstein Physicians Pennypack Pediatrics, et al.

ORDER

AND NOW, this _______day of ________, 2022, upon consideration of Plaintiffs' Motion in Limine to Preclude the St. Christopher Defendants from Offering Expert Opinions That Communications from Hayley Bartkus to the ER Physicians (And Reliance on Those Communications) Met the Standard of Care or Were Appropriate, and Defendants' response thereto, it is hereby **ORDERED** and **DECREED** that the Motion is **GRANTED**.

Based upon the facts and circumstances of this case, Defendants St. Christopher's Healthcare, LLC, American Academic Health System, LLC, Philadelphia Academic Health Holdings, LLC, Philadelphia Academic Health System, LLC, Hayley Bartkus, Erin E. Hassel, M.D., and Pramath Nath, M.D., are hereby **PRECLUDED** from offering the opinions of Steven L. Blumer, MD., Matthew Eisenberg, MD, and John Wiener, MD, that the communications from Ms. Bartkus to the emergency room physicians at St. Christopher's Hospital for Children, and their reliance upon those communications, met the standard of care or were otherwise appropriate.

BY THE COURT:	
MICHAEL M. BAYLSON, J.	

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Lasheena Sipp-Lipscomb and Andres Gardin, Sr., Individually and in their own right and as Parents and Natural Guardians of A G, Jr., a Minor

Civil Action No. 2:20-cv-01926-MMB

Einstein Physicians Pennypack Pediatrics, et al.

PLAINTIFFS' MOTION IN LIMINE TO PRECLUDE THE ST. CHRISTOPHER DEFENDANTS FROM OFFERING EXPERT OPINIONS THAT COMMUNICATIONS FROM HAYLEY BARTKUS TO THE ER PHYSICIANS (AND RELIANCE ON THOSE COMMUNICATIONS) MET THE STANDARD OF CARE OR WERE APPROPRIATE

Plaintiffs move to preclude the Defendant owners/operators of St. Christopher's Hospital for Children (SCHC), Ultrasound Technologist (US Tech) Hayley Bartkus, Erin E. Hassel, MD (the SCHC ER resident physician), and Pramath Nath, MD (the SCHC ER attending physician) (collectively the SCHC Defendants) from offering the expert opinions of Steven L. Blumer, MD, Matthew Eisenberg, MD, and John Wiener, MD, that communications from Ms. Bartkus to the SCHC ED physicians, and their reliance upon those communications, met the standard of care or was otherwise appropriate. Specifically, the record demonstrates that without the supervision or involvement of a radiologist, Ms. Bartkus (an unlicensed US Tech) exceeded the scope of her authority and limits of her training by communicating to SCHC's ER physicians her personal (and incorrect) interpretation of AG Jr.'s scrotal ultrasound—that she was "confident there is good blood flow in both testicles" and "saw evidence of epidymitis on the left side." Likewise, the ER physicians, who understood from Ms. Bartkus that the ultrasound results were "poor" and "extremely limited" by AG Jr.'s "constant motion" (but testified they were not trained to understand the significance of this limitation) relied and acted upon Ms. Bartkus' personal interpretation (without consulting a

radiologist) by, *inter alia*, declining "medication" to calm AG Jr. to obtain better ultrasound images because they were "comfortable" with the "limited results" that Ms. Bartkus reported. Because Ms. Bartkus' communications, and the ER physicians' reliance upon those communications, violated the Pennsylvania Medical Practice Act, and the regulations thereunder (as well as SCHC's policies and procedures), this conduct cannot meet the standard of care as a matter of law. Accordingly, the associated expert opinions offered by the SCHC Defendants on these points are unreliable and inadmissible.

FACTS

Defendant Hayley Bartkus, a nonphysician unlicensed US Tech, was working at SCHC from 10:00 PM on July 23 through 7:30 AM on July 24, 2019. Exhibit 1. Erica Poletto, MD (SCHC's 2019 Interim Radiology Chief) testified that as a nonphysician, Ms. Bartkus had a very limited and circumscribed role—"to acquire the images and provide those images for interpretation." Exhibit 2 at Poletto Tr. (Part 2) 36:2–36:3. Regarding the scope of practice by nonphysician unlicensed US Techs, the American Academy of Radiologists (ACR) directs in its *ACR Practice Parameter for Communication of Diagnostic Imaging Findings* that "It is not appropriate for nonphysicians to provide interpretations and/or generate diagnostic reports (final or preliminary)." Exhibit 3 at p. 2 § II. Ms. Bartkus testified that she understood and agreed with this prohibition. Exhibit 4 at Bartkus Tr. 97:14–21.

Consistent with Ms. Bartkus' limited scope of responsibility and the ACR's prohibition, and "to ensure that all patients seen in the Department of Radiology receive quality diagnostic, radiologic care," in 2019 SCHC had a policy on the "Interpretation of Images" (the **Interpretation Policy**). Exhibit 5 and Exhibit 2 at Poletto (Part 2) Tr. 11:16–12:5. The Interpretation Policy "Related" to

"All [SCHC] Departments" and mandated that:

The Radiologist is responsible for interpretation of all inpatient, outpatient, and emergency department imaging and for interpreting and reviewing imaging and residents' preliminary interpretation(s).

Exhibit 5 ¶ 2. Dr. Poletto explained that this policy and procedure applied to all SCHC radiology studies and all radiologists associated with SCHC (including Defendant teleradiologist Arjun Kalyanpur, MD), and *barred* interpretations by US Techs:

- Q. So going back to the policies and procedures, it says that in number 2 the radiologist is responsible for interpretation of all inpatient, outpatient, and emergency department imaging, and for interpreting and reviewing imaging and resident's preliminary interpretations. Are you talking -- I guess this would apply to all radiologists, whether or not they are in-house at St. Chris or the radiologists such as Teleradiology Solutions, the ones that are offsite?...
- A. My understanding is that all studies that go through the department need to be interpreted by a radiologist.
- Q. And not by an ultrasound technician; is that correct?
- A. Correct.
- Q. Is that correct?
- A. It says radiologist, so it would be a physician.

Exhibit 2 at Poletto Tr. (Part 2) 22:14–23:16.

Confirming the US Tech's limited scope of practice, Defendant Pramath Nath, MD, the SCHC attending ER physician responsible for AG Jr.'s care, explained that it is not appropriate to rely on reports from US Techs, testifying that "we do not base our plan or management based on ultrasound tech." Exhibit 6 at Nath Tr. 55:20–21. SCHC's attending pediatric urologist, Defendant Charles Concodora, MD, forcefully concurred:

- A. I never use the word of an ultrasound technician.
- Q. Why is that?

A. An ultrasound technician is not qualified to read or interpret images. An ultrasound technician is specifically to perform the technical aspect of the ultrasound.

Exhibit 7 at Concodora Tr. at 48:10–16.

- THE WITNESS: As I mentioned to you before, I do not rely upon the comments of an ultrasound tech, and that is also construed upon our residents, that an ultrasound tech has no -- there's no reason an ultrasound tech should be giving an interpretation, and we would never provide patient care based off of an ultrasound tech's interpretation.
- Q. I don't know what the word construed means. What do you mean by construed upon our residents?
- A. Meaning that in training a resident we tell the resident that they are never to rely upon an ultrasound tech's words. That means nothing. They should be relying upon a radiologist.
- Q. So you actually teach them that?
- A. That's part of the residency, is learning how to obtain information and where.
- Q. I'm saying you actually teach them specifically not to rely upon an ultrasound technician, correct?...
- Q. Why don't you answer the question, Doctor?
- A. So during their training a resident is informed on the proper ways of obtaining information, and if a resident were to gather information from an ultrasound tech, that resident would immediately be made aware that that's not the appropriate information to obtain. They would be referred to a radiologist, a radiology read.

Exhibit 7 at Concodora Tr. 75:5–76:22.

Consistent with the Interpretation Policy and the limited role of US Techs, and again "to ensure that all patients seen in the Department of Radiology receive quality diagnostic, radiologic care," in 2019 SCHC also had a policy and procedure for "Direct Communication of Abnormal or Urgent Results" (the **Direct Communication Policy**). Exhibit 8 and Exhibit 2 at Poletto Tr. (Part

2) 29:9–30:13.¹ The Direct Communication Policy "Related" to "All [SCHC] Departments," and mandated "direct" (*i.e.*, by phone or in person) communication between the radiologist (*i.e.*, not the US Tech) and the ordering physician as follows:

- 1. If there are any urgent or significant unexpected findings, the radiologist, fellow, resident or attending shall communicate directly with the referring physician, health care provider, or an appropriate representative who will provide clinical follow-up care. Direct communication includes either in person or by phone.
- 2. Studies requested "STAT" shall result in direct communication with the ordering provider regardless of result....
- 4. Direct communication must be documented in the radiology report, including the name of the physician notified date and time of notification.

Exhibit 8. Pursuant to the terms of this policy, direct communication could not be accomplished by or delegated to nonphysician US Techs.

The limited role of US Techs as well as SCHC's Interpretation and Direct Communication Policies are consistent with Pennsylvania's Medical Practice Act (MPA) and the regulations promulgated thereunder, which prohibits the unauthorized practice of medicine:

No person other than a medical doctor shall engage in any of the following conduct except as authorized or exempted in this act:

- (1) Practice medicine and surgery.
- (2) Purport to practice medicine and surgery.

63 P.S. § 422.10. Further, the MPA directs and limits that:

¹Pursuant the Service Agreement between SCHC and its teleradiology provider, Defendants Teleradology Solutions, P.C. (**TelSol**) and Arjun Kalyanpur, MD, were obligated to follow all SCHC policies and procedures. See Exhibit 9 at § 1.e(v) (TelSol "represent[ed] and warrant[ed] that" TelSol and its physicians including Defendant Arjun Kalyanpur, MD, "shall perform the Services required hereunder in accordance with … all applicable bylaws, rules, regulations, procedures and policies of Hospital and its medical staff") and at Ex. A (TelSol agreed to use "best efforts" to "[r]ender all services … under the applicable governing policies").

A medical doctor may delegate to a health care practitioner or technician the performance of a medical service if:

- (1) The delegation is consistent with the standards of acceptable medical practice embraced by the medical doctor community in this Commonwealth.
- (2) The delegation is not prohibited by regulations promulgated by the board.

63 P.S. § 422.17. The regulations promulgated by the Board further restrict a physician's authority to delegate the performance of a medical service to a US Tech as follows:

- (a) A medical doctor may delegate to a health care practitioner or technician the performance of a medical service if the following conditions are met:
 - (1) The delegation is consistent with the standards of acceptable medical practice embraced by the medical doctor community in this Commonwealth. Standards of acceptable medical practice may be discerned from current peer reviewed medical literature and texts, teaching facility practices and instruction, the practice of expert practitioners in the field and the commonly accepted practice of practitioners in the field.
 - (2) The delegation is not prohibited by the statutes or regulations relating to other health care practitioners.
 - (3) The medical doctor has knowledge that the delegatee has education, training, experience and continued competency to safely perform the medical service being delegated.
 - (4) The medical doctor has determined that the delegation to a health care practitioner or technician does not create an undue risk to the particular patient being treated.
 - (5) The nature of the service and the delegation of the service has been explained to the patient and the patient does not object to the performance by the health care practitioner or technician. Unless otherwise required by law, the explanation may be oral and may be given by the physician or the physician's designee.
 - (6) The medical doctor assumes the responsibility for the delegated

medical service, including the performance of the service, and is available to the delegatee as appropriate to the difficulty of the procedure, the skill of the delegatee and risk level to the particular patient.

- (b) A medical doctor may not delegate the performance of a medical service if performance of the medical service or if recognition of the complications or risks associated with the delegated medical service requires knowledge and skill not ordinarily possessed by nonphysicians.
- (c) A medical doctor may not delegate a medical service which the medical doctor is not trained, qualified and competent to perform.

49 Pa. Code § 18.402. The Medical Board codified these "basic criteria under which a medical doctor may delegate the performance of medical services to nonphysicians" in order "to provide a framework that places patient safety and welfare at the forefront of the medical doctor's decision making process." 34 Pa. Bull. 43 (Jan. 3, 2004). "Any person, or the responsible officer or employee of any corporation or partnership, institution or association, who violates any provisions of this [Medical Practice A]ct or any rule or regulation of the board commits a misdemeanor of the third degree." 63 P.S. § 422.39(a).

At 3:33 AM (EDT) on July 24, 2019, Drs. Hassel and Nath ordered a "stat" scrotal ultrasound to address a possible "Scrotal Torsion." Exhibit 10 and Exhibit 6 at Nath Tr. 60:6–7. Ms. Bartkus explained that "stat" means that "[i]t needs to be done as soon as possible, extremely urgent." Exhibit 4 at Bartkus Tr. 51:4–9. Ms. Bartkus testified that, "[t]he doctor ... indicated on the order that they were concerned for testicular torsion and testicular torsion is universally classified as a stat exam... because it's an emergency situation." Exhibit 4 at Bartkus Tr. 53:3–10. SCHC concedes through its Emergency Medicine expert, Matthew Eisenberg, MD, that "[t]he standard of care requires an US of the scrotum with doppler to evaluate for blood flow to the testicles - a finding that,

if present, excludes a diagnosis of testicular torsion. Testicular torsion, if not identified and corrected rapidly, leads to ischemia, infarct and testicular loss." Exhibit 11 at 2.

At 3:49 AM (EDT), Ms. Bartkus performed the ultrasound. Exhibit 4 at Bartkus Tr. 131:17–132:3, and Exhibit 12. Ms. Bartkus explained that when there is a concern for testicular torsion, she needs to capture ultrasound images that demonstrate "[t]he presence or absence of blood flow" in the testicles. Exhibit 4 at Bartkus Tr. 54:6–55:3. As Ms. Bartkus further explained, when a patient "is squirming or moving around," the movement creates the appearance of "motion artifact" which can be confused with waveforms that indicate actual blood flow in the testicles. Exhibit 4 at Bartkus Tr. 55:5–60:1. During the ultrasound examination, Ms. Bartkus explained that AG Jr. was "very upset" and there was "constant motion" and "a lot of motion artifact." Exhibit 4 at Bartkus Tr. 77:9–78:14.

Dr. Hassel testified that "I recall speaking to the ultrasound tech on the phone, although I don't recall the specifics of that conversation," and at 4:25 AM (EDT) (*before* any radiologist was involved in the case or had even reviewed the images), Drs. Hassel and Nath wrote that they "Spoke to US tech re pt. She said that while it was difficult to examine the pt 2/2 [*i.e.*, secondary to] to the pt moving during US she [Ms. Bartkus] is confident there is good blood flow in both testicles. She reports she saw evidence of epidymitis on the left side." Exhibit 13 at Hassel Tr. 23:3–5, and Exhibit 14.

Although the teleradiologist, Dr. Kalyanpur, testified that patient motion during an ultrasound examination "compromise[s]" the "sensitivity" and "specificity" of the study, (*i.e.*, the ability of the ultrasound to "detect" or "exclude" testicular torsion"), the ER physicians admitted that they did not have the training to understand this phenomena. Exhibit 15 at Kalyanpur Tr. 24:8–25:14. Specifically,

Dr. Nath testified that "I'm not a radiologist, so I did not review the radiology ultrasound films" and when asked whether patient motion compromises either sensitivity or specificity acknowledged that "I'm not a radiologist and I would be unable to comment on that." Exhibit 6 at Nath Tr. 69:10–70:21, 91:18–92:1. Likewise, when questioned about the sensitivity or specificity of an ultrasound examination, Dr. Hassel (a junior resident) acknowledged that "I am not in a position to accurately

answer the question. I'm not a radiologist." Exhibit 13 at Hassel Tr. 67:23–73:24.

Notwithstanding that the ER physicians had no understanding that patient motion compromises ultrasound studies and that the radiologist had not yet even reviewed the films, they told Ms. Bartkus that they were "comfortable" with her review and the "limited results" she reported, and relied upon Ms. Bartkus' comments to guide their care. Specifically, Drs. Hassel and Nath who wrote at 4:34 AM (EDT) that they "Relayed [to the urology resident Defendant Eric Cho, MD] that US tech was NOT concerned for torsion, saw signs of epididymitis (LEFT)." Exhibit 14. Drs. Hassel and Nath further documented their reliance on Ms. Bartkus' read of the ultrasound in their "Medical Decision Making" by stating their "Rationale" to be "U/S of poor quality, however, U/S tech reported good flow to both testicles during exam. Imaging did reveal swelling consistent with epididymitis." Exhibit 14. Specifically, the ED Note authored and electronically signed by Drs. Nath and Hassel states:

Medical Decision Making

Differential Diagnosis: Testicular torsion, epididymitis, inguinal hernia, orchitis.

Rationale: Left testicle erythematous, warm, swollen. No h/o of fever, parotitis, n/v, dysuria, hematuria. U/S of poor quality, however, U/S tech reported good flow to both testicles during exam. Imaging did reveal swelling consistent with epididymitis..

Documents reviewed: None available.

07/24/2019 04:25 Spoke to US tech re pt. She said that while it was difficult to examine the pt 2/2 to the pt moving during US she is confident there is good blood flow in both testicles. She reports she saw evidence of epidymitis on the left side.

07/24/2019 04:34 Consulted urology re pt. Relayed that US tech was NOT concerned for torsion, saw signs of epididymitis (LEFT). Informed urology of plan to treat pt with motrin Q8 for 5 days and have f/u with pediatrics. Urologist reported that he would view images and call back.

Exhibit 14. See also Exhibit 13 at Hassel Tr. 13:1–4 (note was jointly authored), Exhibit 6 at Nath Tr. 29:3–10, 81:13–24 (Nath was present with Hassel for services performed).

Only *after* the foregoing, at 4:40 AM, the ultrasound images and Ms. Bartkus' associated Tech Comments were uploaded to the teleradiologist, Dr. Kalyanpur, in India. In her Tech Comments, Ms. Bartkus relayed to Dr. Kalyanpur her interpretation of the study and her discussion with the ER physicians who had advised that they declined to medicate AG Jr to obtain better images because they were "comfortable" with the "limited results" she reported (without the input or supervision of a radiologist).

* E X T R E M E L Y L I M I T E D S T U D Y , P T INCONSOLABLE/SCREAMING/CONSTANT MOTION

-RT [Right] TESTIS WNL [Within Normal Limits] WITHIN ING [Inguinal] CANAL, FLOW IMAGING LIMITED BUT VISUALIZED

-LT [Left] TESTIS FLOW IMAGING LIMITED BUT SEEN, SIGNIFICANT INCREASE OF FLOW VISUALIZED IN AREA OF LT EPI [Epididymis]

*SPOKE TO ED ABOUT LIMITED RESULTS, WERE COMFORTABLE AND CHOSE NOT TO MEDICATE PT

Exhibit 4 at Bartkus Tr. 74:19–75:11, Exhibit 16, and Exhibit 17 (emphasis supplied).²

Notwithstanding these events, Ms. Bartkus now concedes that her statements to the ER

²TelSol's Audit Data (Exhibit 16) uses Coordinated Universal Time (UTC), such that the upload time of 08:40:10 AM UTC converts to 4:40 AM Eastern Daylight Time (EDT). Ms. Bartkus' Tech Comments produced by TelSol (Exhibit 17) use India Standard Time (IST), such that the upload time of 2:10 PM IST converts to 4:40 AM EST.

physicians would have been inappropriate because "I'm incapable as a sonographer of giving results for anything" and "anything I would say would be irrelevant."

Q. [T]his is Plaintiff's Exhibit P-10, ...and you see here they're talking about medical decision making.... It says here ultrasound of poor quality.... Did you understand that the ultrasound was of poor quality?...

THE WITNESS: No.

Q. Did you think the ultrasound was good quality?

THE WITNESS: I -- I'm not sure of that....

- Q. Then it says ultrasound tech reported good blood flow to both testicles during the exam. Did you say that?
- A. I don't remember -- I don't remember....
- Q. Did you tell the physician that imaging did reveal swelling consistent with epididymitis?
- A. I don't remember, but -- I don't remember....
- Q. Is that the kind of statement that you would make?
- A. No, that statement is a diagnosis. Epididymitis is a diagnosis....
- Q. It says 4:25, that's 4:25 a.m. spoke to ultrasound tech re patient.... It then says she, meaning you, is confident there is good blood flow in both testicles.... Is that something that you would have conveyed to an emergency room doctor, that you're confident there's good blood flow in both testicles?...

THE WITNESS: I would not convey this to a doctor, these statements....

- Q. And then it says "she reports she saw evidence of epididymitis on the left side." Is that something you would have reported to the doctor?
- A. No....
- Q. ... When it says "she reports she saw evidence of epididymitis on the left side," that would be a diagnosis, would it not?...
- THE WITNESS: I don't know. I would not have said these words to a physician. This is not my common practice. As a sonographer I don't do this. I don't say these things.
- Q. Let's go to the next line. This is now at 4:34 a.m... [I]t says relayed tech was not, and the word not is spelled in all capital letters, concerned for torsion. Did you ever state that to the emergency room doctor?

- A. I don't remember the conversation I had with the emergency room doctor.
- Q. Would that be a diagnosis? ... The statement that she was not concerned for torsion?...
- THE WITNESS: Nothing that I say is a diagnosis. As a sonographer there's nothing that I could say that would be a diagnosis.
- Q. Would it be your interpretation?
- A. No. I can't -- an interpretation is the same thing. As a sonographer nothing I say is an interpretation or a diagnosis.
- Q. So it wouldn't be relevant whether or not you were concerned for testicular torsion; is that correct?...
- THE WITNESS: It would be irrelevant. My opinion would be irrelevant or anything I would say would be irrelevant....
- Q. If it was irrelevant -- if your opinion is irrelevant or your statements are irrelevant, do you know why they'd be reported in this note?...
- THE WITNESS: I don't know. I don't know....
- THE WITNESS: ...I do not give results. I cannot give a result. I would never give a result as a sonographer.
- Q. And that's because you never would have relayed that you were not concerned for torsion?...
- THE WITNESS: I would not give -- I'm incapable as a sonographer of giving results for anything.
- Q. So, therefore, as you said before, you did not relay that you were not concerned for torsion?...
- THE WITNESS: As a sonographer I'm unable to give results and did not -- cannot give results and did not give results.

Exhibit 4 at Bartkus Tr. 106:23-121:19. Dr. Kalyanpur, through his expert witness Scott Berger,

MD, also acknowledges that Ms. Bartkus' communication of the "RESULTS" was not appropriate:

INAPPROPRIATE COMMUNICATION BY TECHNOLOGIST: It is universally understood in the field of radiology that technicians are not credentialed to render interpretations of exams – that is not part of their training and they are not qualified to do so. In that regard, Ms. Bartkus was performing a function that would have required a physician's credentials.... [T]echnologists do not have either the fund of knowledge or the training to render interpretations of the ultrasound exams.

Exhibit 18 at 19 (emphasis supplied).

At 5:33 AM, Dr. Kalyanpur created his Preliminary Report which he faxed to SCHC at 5:35 AM stating:

Findings:

Significantly limited evaluation due to noncooperative patient.

Right: The right testicle measures $1.6 \times 0.7 \times 1$ cm and demonstrates normal echogenicity and Doppler flow signal. The right testis is seen in the right inguinal canal, possibly retractile testis. The right epididymis appears grossly unremarkable. There is no hydrocele.

Left: The left testicle measures 1.6 x 1.1 x 1.1 cm and demonstrates normal echogenicity and Doppler flow signal. The left epididymis measures 0.4 cm and demonstrates increased flow on Doppler evaluation. There is no hydrocele.

Exhibit 19. From these findings, Dr. Kalyanpur formed the impression that:

Impression:

- 1. Markedly limited evaluation as described.
- 2. No evidence of testicular torsion on this limited evaluation.
- 3. Increased flow to the left epididymis. In the appropriate clinical setting, epididymitis cannot be excluded. Recommend clinical correlation and follow.

Exhibit 19.

Regarding the information that he received from Ms. Bartkus that she "SPOKE TO ED ABOUT LIMITED RESULTS, WERE COMFORTABLE AND CHOSE NOT TO MEDICATE PT," Dr. Kalyanpur testified that:

- THE WITNESS: I would understand this to mean that the emergency physicians felt that it wasn't of significant concern that the examination needed to be repeated with medication.
- Q. And medication you would understand to be for sedation?
- A. Correct.

Exhibit 15 at Kalyanpur Tr. 28:4-19. Regarding Ms. Bartkus' comment and Dr. Kalyanpur's

understanding, Dr. Kalyanpur's expert radiologist, Scott Berger, MD, explains:

the comment conveys the mistaken impression to TS [Teleradiology Solutions owned by Dr. Kalyanpur] that the ER doctors were so confident of their diagnosis that, even without the images having been interpreted, when asked if better images needed to be obtained with the patient sedated, their reply was "no." In reality, the ER doctors were not confident in the diagnosis of epididymitis solely upon clinical grounds, and they were relying on the US, albeit, the interpretation rendered by a non-qualified technologist.

Exhibit 18 at 20.

There is no reference in the medical chart that Dr. Kalyanpur's Preliminary Report was reviewed or even seen by the ER physicians, and Dr. Kalyanpur (who was in India) never spoke to anyone at SCHC.

- Q. And did you ever speak by telephone on July 24, 2019, with anyone at St. Christopher's Hospital?
- A. I don't recall speaking with anyone.
- Q. Did you ever e-mail or text message or message in any way with anyone at St. Christopher's Hospital on July 24, 2019, the date of the incident?
- A. No.
- Q. So the only communication from Teleradiology Solutions to the hospital was the report that was faxed, the preliminary report that was faxed by Teleradiology Solutions and electronically signed by you, that was faxed to the hospital, that's the only communication from your end that was given to the hospital; is that correct?
- A. I believe that is correct.

Exhibit 15 at Kalyanpur Tr. 105:20–106:12. Instead, the only "direct communication" with the ER physicians was the inappropriate communication with Ms. Bartkus.

Hours after AG Jr. was discharged, Dr. Kalyanpur's Preliminary Report was reviewed by the attending onsite radiologist at SCHC who determined that "Normal smooth arterial and venous waveforms are not documented" on the ultrasound and a repeat ultrasound was "recommended to

exclude testicular torsion and document normal blood flow in the testes." Exhibit 12. A subsequent investigation by Dr. Poletto (and agreed with by Dr. Kalyanpur) found that "The waveforms in the left testis are not real- they are related to motion.... As per the technologist, the ED would not sedate. The tech was counseled about this case." Exhibit 20.

ARGUMENT: The SCHC Defendant Experts May Not Opine That Conduct Violating the Medical Practice Act (And Regulations Thereunder) Is Appropriate or Meets the Standard of Care

"The proponent of the expert testimony has the burden of establishing its admissibility by a preponderance of the evidence..... 'Under Rule 702, the district court acts as a 'gatekeeper' to ensure that 'the expert's opinion [is] based on the methods and procedures of science rather than on subjective belief or unsupported speculation." *myService Force, Inc. v. Am. Home Shield*, No. 10-6793, 2014 U.S. Dist. LEXIS 61207, *13 (E.D. Pa. May 1, 2014) (Padova, J.) (citations omitted). In this regard, "The expert's testimony must 'fit' under the facts of the case so that 'it will aid the jury in resolving a factual dispute." *Id.* at *16. Moreover, when an expert's "opinions conflict with the controlling law ..., they are unreliable and will only serve to confuse the jury. *United States v. Arrow-Med Ambulance, Inc.*, No. 17-CR-73-JMH, 2018 U.S. Dist. LEXIS 66556, *10 (E.D. Ky. Apr. 20, 2018). See also *Tsao v. Ferring Pharms.*, No. 4:16-CV-01724, 2018 U.S. Dist. LEXIS 237560, *39 (S.D. Tex. Apr. 19, 2018) (excluding as unreliable expert opinion that conflicts with statutes and regulation). Since the opinions of the SCHC Defendants' experts in this case are ground in a construct that violates Pennsylvania law—*i.e.*, that the US Tech communications to the ER physicians (and the reliance upon same) were appropriate and meet the standard of care—such

proposed testimony is unreliable, will only serve to confuse the jury, and must be precluded.³

³Steven L. Blumer, MD (SCHC's radiology expert) opines:

I strongly disagree with Plaintiffs experts' opinions that technologist Ms. Bartkus did anything wrong or exceeded the scope of her practice. I do not agree that Ms. Bartkus was practicing medicine without a license. She performed the ultrasound, created her comments, and communicated her observations with the ER with the understanding that a radiology report would follow; all standard of care....It is my opinion that St. Christopher's Hospital for Children and Ms. Bartkus complied with the standard of care.

Exhibit 21 at 1, 2. Likewise, Matthew Eisenberg, MD (SCHC's emergency medicine expert) opines:

It is common to encounter challenges when trying to perform a medical procedure on a young child, particularly a young child who is in pain. It is both common and good care to have ongoing conversations with a radiology technologist (or any other medical professional) attempting to perform a medical procedure on a frightened young child to assess whether the procedure can be adequately completed. Often times, behavioral interventions are attempted (e.g. attempting to distract the patient with a tablet computer), medications that provide anxiolysis may be given, and rarely procedural sedation may be necessary, though almost never for an ultrasound. Dr. Hassel documented these conversations, and noted that while it was a challenging exam, the technologist reported being able to obtain all of the required images. This report does not replace the judgment of the radiologist reading the study, nor did it inform Dr. Hassel and Dr. Nath's medical decision making. It is merely a report of a technologist that she was able to complete the study within the necessary quality parameters. In practice, technologists frequently make comments on these types of studies and, in fact, there is a section in the EMR for them to do so. The radiologist then makes a decision if the ultrasound is of sufficient quality and renders his interpretation accordingly....

Repeating a radiology study, or performing procedural sedation to complete a study, is only indicated when a study is "non-diagnostic," meaning the clinical question posed by the person ordering the study cannot be answered. Given the report of blood flow to both testes, there would have been no reason for Dr. Hassel and Dr. Nath to subject the patient to procedural sedation, keep him for many more hours in the ED for a second radiologist to review the images, or repeat the ultrasound.

Exhibit 11 at 2, 5. Additionally, John S. Wiener, M.D. (SCHC's pediatric urology expert) opines:

The sonographer performed her duties appropriately....It is not outside the standard of care for the sonographer to inform physicians of their preliminary findings while the radiologist is reviewing images to determine if they are adequate for a radiologist to give his or her impression. This represents standard and customary communication among the health care team.

Exhibit 22 at 4.

In its earlier opinions in this case, this Court outlined certain parameters of the MPA and concluded that:

- The Acts⁴ "clearly proscribe" an unlicensed technician from diagnosing a patient based on an ultrasound without meaningful supervision;
- While the Acts include a safe harbor for properly supervised practice of medicine, the practice is not properly supervised where the physician allegedly relied on an unlicensed individual's diagnosis at face value, heedless of the reviewing doctors' comments; and
- If a doctor allegedly "relied on the ultrasound technician's assessment of the sonogram," other licensed doctors' outside review does not break the causal chain between the unlawful diagnosis and the plaintiffs' resulting injury.

Sipp-Lipscomb v. Einstein Physicians Pennypack Pediatrics, No. 20-1926, 2020 U.S. Dist. LEXIS 234910, *10 (E.D. Pa. Dec. 15, 2020) (Sipp-Lipscomb II) (citing Sipp-Lipscomb I, 2020 U.S. Dist. LEXIS 132943 (E.D. Pa. July 28, 2020)).⁵

Now that discovery is closed, it is beyond dispute the Ms. Bartkus is an unlicensed nonphysician US Tech and was unsupervised by any radiologist when she interpreted the ultrasounds images and she reported her interpretation to Drs. Nath and Hassel. It is also undisputed that at the

⁴At Plaintiff's urging, the Court addressed similar prohibitions under the MPA and the Osteopathic Medical Practice Act. However, because it appears after discovery that no osteopathic physician was involved in the care and treatment of AG Jr., Plaintiffs only address the application of the MPA and the regulations thereunder.

⁵Specifically, the MPA charges that "[n]o person other than a medical doctor shall...practice medicine and surgery [or] [p]urport to practice medicine and surgery." 63 P.S. § 422.10. The MPA also allows medical doctors to "delegate to a healthcare practitioner or technician the performance of medical service if...[t]he delegation is consistent with the standards of acceptable medical practice embraced by the medical doctor community in this Commonwealth" and not otherwise prohibited. 63 P.S. § 422.17(a). Applicable regulations clarify that a medical doctor delegating "the performance of a medical service" must "ha[ve] knowledge that the delegatee has education, training, experience and continued competency to safely perform the medical service being delegated." 49 Pa Code § 18.402(a)(3). Likewise, "[a] medical doctor may not delegate a medical service which the medical doctor is not trained, qualified and competent to perform." 49 Pa Code § 18.402(b).

time she reported her interpretation, no radiologist had reviewed the images or the case. Ms. Bartkus also admits, and all fact witnesses concur, that she was "incapable" of "giving results." It is also undisputed that neither Drs. Nath nor Hassel were trained or competent to perform an ultrasound examination or read ultrasound images. Nonetheless, because they were "comfortable" with the "limited results" reported by Ms. Bartkus without the supervision or input of a radiologist, Drs. Nath and Hassel decided not to medicate AG Jr. in order to calm him down so that better images could be captured. Finally, it is also undisputed that Dr. Kalyanpur had no "direct communication" (i.e., by phone or in person") with the ordering physicians (Drs. Nath and Hassel). The only "direct communication" that transpired was the phone call between Ms. Bartkus and the ER physicians.

Based on these facts, it is clear that Ms. Bartkus did not have (and the ER physicians knew she did not have) the "education, training, experience and continued competency to safely" interpret and report to the ER physicians ultrasound results without the supervision of a radiologist. 49 Pa Code § 18.402(a)(3). Likewise, because neither Dr. Nath nor Dr. Hassel were "trained, qualified and competent to perform" ultrasound examinations, they could not lawfully delegate the interpretation of ultrasound images to an unsupervised nonphysician unlicensed US Tech (who acknowledged she was "incapable") and therefore could not rely upon her unsupervised interpretation. 49 Pa Code § 18.402(b).

Additionally, there is no evidence that Defendants "explained to the patient" (or provide any meaningful opportunity to "object") "[t]he nature of the service and the delegation of the service" to US Tech Bartkus. 49 Pa Code § 18.402(a)(5). In this regard, there is no evidence that anyone explained to AG Jr.'s parents, *inter alia*, that the decision not to medicate was based upon an interpretation delegated to an unsupervised US Tech. Likewise, no medical doctor "determined that

the delegation to a health care practitioner or technician does not create an undue risk to the

particular patient being treated." 49 Pa. Code § 18.402(a)(4).

These violations of the MPA and the related regulations cannot be cured by expert opinion

that the conduct otherwise met the standard of care. Because the conduct is unlawful, any expert

opinion claiming that the conduct is appropriate or meets the standard of care would only confuse

the jury and is otherwise unreliable at a matter of law. Accordingly, it would be grossly improper for

SCHC's experts to opine that the standard of care, as applied to the facts of this case, permitted Ms.

Bartkus to communicate as she did with the ER physicians and the ER physicians to rely and act upon

those communications.

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Date: May 25, 2022

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⁶It is noteworthy that Matthew Eisenberg, MD (SCHC's emergency medicine expert) and John Wiener, MD (SCHC's pediatric urology expert) are not licensed to practice medicine in Pennsylvania and therefore would have no experience with Pennsylvania's MPA or regulatory framework, and the relevant prohibitions thereunder.

CERTIFICATE OF SERVICE

I, DAVID E. JOKELSON, hereby certify that on May 25, 2022, a true and correct copy of Plaintiffs' Motion in Limine to Preclude the St. Christopher Defendants from Offering Expert Opinions That Communications from Hayley Bartkus to the ER Physicians (And Reliance on Those Communications) Met the Standard of Care or Were Appropriate was served *via* the Court's ECF System upon the following:

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